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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/251,133 02/16/99 SHAH

G 70009590-001

EXAMINER

HM12/0327

DAVID G ROSENBAUM  
SONNENSCHN NATH & ROSENTHAL  
8000 SEARS TOWER  
233 SOUTH WACKER DRIVE  
CHICAGO IL 60606-6404

HOLLERAN, A

ART UNIT

PAPER NUMBER

1642

13

DATE MAILED:

03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/251,133

Applicant(s)

Shah, G.V.

Examiner

Anne Holleran

Group Art Unit

1642



☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-5 \_\_\_\_\_ is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-5 \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1, drawn to polynucleotides, classified in class 536, subclass 23.5.
  - II. Claims 2, 3 and 5, drawn to polypeptides and compositions, classified in class 530, subclass 300 or 350.
  - III. Claim 4, drawn to methods for delivering a detectable label or cytotoxic agent, classified in class 424 or 514 subclass 178.1 and 2, respectively.

2. The inventions are distinct, each from the other, for the following reasons:

Inventions I and II are each drawn to separate and distinct chemical products. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute apparently distinct inventions for the following reasons: the polynucleotides of groups I and the peptides and compositions of group II are chemically distinct products unrelated in sequence and separately classified having separate fields of search. Other than the fact that the polypeptides and polynucleotides are derived from the same cell type, the polynucleotides of group I and the compositions and peptides of group II have no relationship to each other chemically. The function and existence of either DNA or protein is not dependent on the existence of the other. The products of each group (I or II) can be independently synthesized by chemical means. Each of the products have separate, unrelated uses and are not disclosed as

being capable of use together. Further, it would place undue burden on the examiner to examine several independent inventions in one application.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the peptides of invention II can be used to make antibodies and can be used in in vitro methods of purifying antibodies. These methods are materially different processes than a process of treatment using compositions comprised of the peptides of Invention group II.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and recognized divergent subject matter and because searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

3. The claims of Groups I, and <sup>II</sup>III are each drawn to multiple separate and distinct polynucleotides and polypeptides, respectively. This constitutes recitation of an implied, misjoined Markush group that contains multiple, independent and distinct inventions. Each of the different polynucleotides or polypeptides is independent and distinct because no common structural properties are shared. Accordingly, the claims of each of Groups I, and <sup>II</sup>III are subject to restriction under 35 U.S.C. 121.

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Upon election of Group I, Group II or Group III, Applicant is additionally required to elect a single polynucleotide or polypeptide. In the case of Group I, Applicant is required to elect one polynucleotide of SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5. In the case of Groups II and III, Applicant is required to elect one polypeptide of SEQ ID NO: 1, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8, SEQ ID NO: 9, SEQ ID NO: 10, SEQ ID NO: 11 and SEQ ID NO: 12.

This requirement is not to be construed as a requirement for an election of species, since each of the polynucleotides or polypeptides recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

4. This application contains claims directed to the following patentably distinct species of binding agent:

- a. antibodies
- b. D-peptides
- c. peptidomimetic compound
- d. aptamers comprising DNA, RNA or modified nucleoside analogs

Upon election of Group II, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon,

including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Applicant is advised that the reply to this requirement, to be complete, must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892.

Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

AH

Anne L. Holleran  
Patent Examiner  
March 13, 2001

AM  
ANTHONY G. CAPUTA  
JUNIOR PATENT EXAMINER  
TECHNOLOGY CENTER 1000